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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,298	06/20/2003	Julian N. Nikolchev	016355-002580US	6671

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EXAMINER

BENNETT, HENRY A

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/600,298

Applicant(s)

NIKOLCHEV ET AL.

Examiner

Henry Bennett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-21 is/are allowed.
- 6) ☒ Claim(s) 22-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Henry Bennett
Supervisory Patent Examiner
Group 3700

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After reviewing of the file history of the present application , It has been determined that the effective date for claims 22-81 in the present application is September 24, 1997 which corresponds to the filing date of applicants provisional application 60/059861. A key factor in making this decision was the review of applicants prior applications 08/474229 (now US Patent 6176240) and application 08/475252 which have an effective filing date of June 07, 1995 and provisional application 60/059861 which has an effective date of September 24, 1997.

Claims 24 and 81 in the present application are representative of the critical limitations on which the effective filing date of claims 22-81 was decided.

Claim 24 (Previously Presented) A contraceptive device, comprising

a) a tubular body which is expandable from a first tubular configuration to a second larger tubular configuration to facilitate securing at least a portion of the tubular body to a wall portion defining at least in part a lumen of a patient's reproductive system and which has an open framework facilitating the in growth of tissue cells; a member within the expandable tubular body which is configured to support tissue growth.

Claim 81. (New) A contraceptive device, comprising

a) a body expandable within a lumen of a patient's reproductive system from

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a first tubular configuration to a second tubular configuration, the second tubular configuration having a larger cross-sectional profile than the first tubular configuration relative to an axis of the contraceptive device to facilitate securing at least a portion of the body to a wall portion defining at least in part a lumen of a patient's reproductive system, the body comprising a helical coil and allowing the in growth of tissue

b) a material disposed at least in part within the expandable body so as to incite tissue in-growth.

Applicant has asserted that he has a basis for all of the limitation recited of claims 24 and 81 in his prior applications 08/474229 (now US Patent 6176240) and application 08/475252. After a careful review of these applications, it has been determined that applicant has a basis for **a contraceptive device that expands from a first to a larger configuration** but he does not have a basis for **"a contraceptive device that has a first tubular configuration and expands to a second larger configuration about an axis of the contraceptive device" or "expansion from a first tubular configuration to a second larger tubular configuration"**. The examiner is of the opinion that in applicants prior applications and patent, the disclosed contraceptive device does in fact expand in size but it does not expand about a **tubular axis of the contraceptive device** to lodge itself in the reproductive tract. It has also been determined that in the in applicants previous disclosures in 08/474229 (now US Patent 6176240) and

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application 08/475252, the inner diameter of the initial tubular member appears to remain the same in the expansion to the second larger tubular configuration. These limitations are critical to applicants assertion that he has a basis for claims 24 and 81 in his prior disclosures. It appears that a proper interpretation of applicant claims to **"expansion to a larger tubular configuration"** should be evaluated in light of applicants previous disclosures which supports a larger configuration but not a larger tubular configuration where the inside diameter of the first tubular members is increased as a result of the expansion.

It is also important to note that in claim 81 it is not clear which "axis" applicant is referring to. It is presumed to be the longitudinal axis given that this interpretation would result in the securing of the tubular contraceptive device to the wall of the reproductive lumen passage.

In light of the above positions taken by the examiner the following rejections now apply

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 81 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 81 recites "an axis of the contraception device" This limitation is considered or to be indefinite in that the exact an about which the device expands has not been specified.

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1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Given that it has been determined by the examiner that claims 22-81 have an effective filing date of September 24, 1997, the following rejection applies

2. Claims 22-81 rejected under 35 U.S.C. 102(e) as being Anticipated by Callister et al. **US 7073504**.

Callister et al discloses A contraceptive device, in Figs 1-18 that comprises

a) a body expandable within a lumen of a patient's reproductive system from a first tubular configuration to a second tubular configuration, the second tubular configuration having a larger cross-sectional profile than the first tubular configuration relative to an axis of the contraceptive device to facilitate securing at least a portion of the body to a wall portion defining at least in part a lumen of a patient's reproductive system, the body comprising a helical coil and allowing the in growth of tissue

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b) a material disposed at least in part within the expandable body so as to incite tissue in-growth.

Claims 12-21 are allowable.

Should applicant decided to provoke an interference with application 08/770123 (now US Patent 7073504) please consider procedures set forth in MPEP 2304 for the most recent requirements.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry Bennett whose telephone number is 571-272-4791. The examiner can normally be reached on Monday through Friday from 8:00 am until 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennnett can be reached on (703) 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hab



Harry Bennett
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